DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M323111

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

via Federal Express

December 1, 1999

MQSA Facility ID: 196121
Inspection ID: 1961210005
FDA Reference #: 2952183

Barbara Faller
Administrator
Central Valley Medical Group
Chowchilla District Memorial Hospital
P.O. Box 1027
Chowchilla, California 93610

Dear Ms. Faller:

We are writing to you because on September 28, 1999, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious problems involving the mammography procedures performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility, which represent departures from Title 21, Code of Federal Regulations (CFR), Part 900.

Level 1: Mammograms were processed in processor, [redacted] located in room one, when it was out of limits on thirty-two days. {21CFR§900.12(e)(1)}

Level 1: Processor quality control records were missing for thirty-two consecutive days for processor, [redacted] located in room one. We were unable to verify that the processor was operating within limits during that time. 21CFR§900.12(e)(1)}

Level 1: Processor quality control records were missing for eight out of eight days (100%) and for five out of five days (100%) of operation in months April 1999 and July

1999, respectively, for processor, [redacted], located in room one. For these periods of time, we were unable to verify that the processor was operating within limits. {21CFR§900.12(e)(1)}

Level 1: Phantom quality control records were missing for twelve weeks for unit 1, [redacted] located in MAMMO room. {21CFR§900.12(e)(2)}

Level 2: Not all positive mammograms were entered in the tracking system. {21CFR§900.12(f)(1)}

Level 2: There were no examples of or attempts to get biopsy results. {21CFR§900.12(f)}

Level 2: There is no written procedure for infection control. {21CFR§900.12(e)(13)}

Level 2: Corrective action for a failing image score (before further exams) was not documented for unit 1, [redacted], located in MAMMO room. {21CFR§900.12(d)(2)}

Level 2: Corrective actions for processor quality control failures were not documented at least once for processor, [redacted], located in room one. {21CFR§900.12(d)(2)}

Level 2: Seven of ten random reports reviewed did not contain an assessment category. {21CFR§900.12(c)}

Level 2: The measured fog density is equal to 0.29 for darkroom one. {21CFR§900.12(e)(4)(i)}

Level 2: The radiologic technologist, [redacted] did not meet the continuing education requirement of having completed a minimum of fifteen Continuing Education Units (CEUs) in mammography in a thirty-six month period. {21CFR§900.12(a)(2)(iii)}

Level 2: The radiologic technologist, [redacted] did not meet the continuing education requirement of having completed a minimum of fifteen Continuing Education Units (CEUs) in mammography in a thirty-six month period. {21CFR§900.12(a)(2)(iii)}

Level 2: The interpreting physician, [redacted] did not meet the continuing education requirement of having completed a minimum of fifteen Continuing Mammography Education (CME) credits in mammography in a thirty-six month period. {21CFR§900.12(a)(1)(ii)(B)}

Level 2: The time period between the previous and current medical physicist surveys for x-ray unit 1, [redacted] exceeds fourteen months. {21CFR§900.12(e)(9)(i)}

Level 2: There is no written procedure for handling consumer complaints. {21CFR§900.12(h)(1)}

Level 2: There was no designated reviewing interpreting physician. {21CFR§900.12(f)(3)}

Level 2: The phantom quality control is not adequate for unit 1, [redacted], located in room MAMMO, because the operating level for background density was < 1.20. {21CFR§900.12(e)(2)(i)}

Additionally, the inspection revealed the following level 3 findings at your facility:

Level 3: The quality assurance program is inadequate because the following items were either missing, incomplete, or not clearly defined:

- Personnel responsibilities. {21CFR§900.12(d)(1)}
- Quality control test procedures. {21CFR§900.12(d)}

Level 3: The fixer retention quality control is not adequate for processor [redacted]. The missing or incomplete items are listed below:

- The fixer retention quality control records were not done at the required frequency, which is quarterly. {21CFR§900.12(e)(3)(i)}
- Corrective action was not documented at least once. {21CFR§900.12(d)(2)}

Level 3: Compression device quality control is not adequate for unit 1, [redacted], located in MAMMO Room because:

- The quality control records were not done at the required frequency, which is semiannually. {21CFR§900.12(e)(4)(iii)}
- Corrective action was not documented before further exams. {21CFR§900.12(d)(2)}

Level 3: The repeat analysis quality control is not adequate because:

- Quality control was not done at the required frequency, which is quarterly. {21CFR§900.12(e)(3)(ii)}
- There was no evaluation done. {21CFR§900.12(e)(3)(ii)}
- Corrective action within thirty days was not documented. {21CFR§900.12(d)(2)}

Level 3: The screen film contact quality control is not adequate because:

- Quality control was not done at the required frequency, which is semiannually. {21CFR§900.12(e)(4)(ii)}
- Not all mammography cassettes in use were tested. {21CFR§900.12(e)(4)(ii)}
- The 40-mesh copper test tool was not used. {21CFR§900.12(e)(4)(ii)}
- Corrective action was not documented on at least one occasion. {21CFR§900.12(d)(2)}

Level 3: The darkroom fog quality control is not adequate for Darkroom because:

- The quality control records were not done at the required frequency, which is semiannually. {21CFR§900.12(e)(4)(i)}
- The background density was < 1.20. {21CFR§900.12(e)(4)(i)}
- Corrective action was not documented at least once before further exams. {21CFR§900.12(d)(2)}

The specific problems noted above appeared on your initial MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Since the first three of the four Level 1 noncompliances listed in this letter and in your initial inspection report occurred prior to the implementation of the Final Regulations on April 28, 1999, your MQSA Facility Inspection Report will be revised to classify those three Level 1 noncompliances as Level 2. We are making this change, since the FDA had different criteria for Level 1 findings that occurred prior to April 28, 1999.

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and represent serious violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel)
510-337-6702 (fax)

Please send a copy of your response to:

Jan Hillman-Ortiz, MQSA Inspector (2178)
State of California
Department of Health Services
Radiologic Health Branch
P.O. Box 942732
601 N. 7th Street, MS-178
Sacramento, CA 94234-7320

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting

the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. John M. Doucette at 510-337-6793.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
Director
San Francisco District

cc:
Bonnie Bessemer, MQSA Inspection Program Monitor
Jan Hillman-Ortiz, MQSA Inspector (2178)
Pamela A. Wilcox-Buchalla, R.N., M.B.A.